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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,898	11/28/2001	Scott R. Presnell	00-108	1509

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ZymoGenetics, Inc.
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EXAMINER	
KAUFMAN, CLAIRE M	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 04/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/995,898	PRESNELL ET AL.	
	Examiner	Art Unit	
	Claire M. Kaufman	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/20/04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *17-21,23 and 25-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16,22 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-36* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/12/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I in the paper filed is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Specification

The disclosure is objected to because of the following informalities: The symbol "□" incorrectly appears throughout the specification. Below are two examples, but the specification should be carefully checked for others:

in lines 16-18 on page 143, "amounts of each nucleotide, 5□1 of 10x CDNA PCR Reaction Buffer (Clonetech), 3□1 DNA from the RT reaction, 0.5□1 Advantage2 Polymerase (Clonetech), made to a final volume of 50□1 with water...."

on p. 128, line 10, "(Fc□ specific)"

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-16, 22 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification appears to provides a credible use on page 141 (lines 15-18) for the polynucleotide of SEQ ID NO:1, which is screening for colon, endometrial and ovarian carcinomas. This use may extend to SEQ ID NO:18 and 20 as well as the fragments set forth in claim 2 of the instant application, but this cannot be confirmed with the information present in

the specification. Particularly, the use relies on the ability to carry about *in situ* hybridization in accordance with the method appearing on page 141 in the first two paragraphs or with a method that would provide identical results. *In situ* was carried out with a probe only defined as a 0.7kb fragment from the 3'UTR end of plasmid DNA 100933. No where does the specification describe plasmid DNA 100933. It is not clear if it is a part of SEQ ID NO:1 or a part of the genomic DNA, for example. The sequence of the probe is not provided. It is not clear if the use would extend to all fragments listed in claim 2 because it is not clear if those sequences were comprised by the probe. Nor is it clear if other regions of SEQ ID NO:1 would produce the same diagnostic results, for example, a 0.6kb fragment beginning at the ATG start site. The specification provides no examples or guidance directed toward polynucleotides that could be used for the disclosed carcinoma screening. Claims 1, 3-16, 22 and 24 are drawn to polyncleotides encoding particular fragments of SEQ ID NO:2, 19 and 21. For these claims, unless one skilled in the art would reasonably expect that the encoding polynucleotides could be used for the disclosed diagnostic purposes discussed above, they would not be enabled. That is, because of the degeneracy of the genetic code, a polynucleotides encoding a protein may share very little sequence identity with each other. For example, the signal sequence of SEQ ID NO:2 (claim 13(a)), is 20 amino acids long. There is one disclosed naturally occurring polynucleotide sequence encoding this; but, conservatively assuming only 1 out of every three nucleotides is changed within each codon while maintaining the encoded sequence, this results in a 60 base long polynucleotide that shares only 66% identity with the disclosed sequence. Values could realistically be even lower, and one skilled in the art would not reasonably expect that an *in situ* probe with such low identity could be used reliable to detect what is described as "weak" staining when the original probe was, presumable, 100% identical to the polynucleotide (or fragment thereof) being detected in the cell sample. For these reasons, even if the full-length zcytor DNAs were enabled, encoding polynucleotides would not be enabled, and the fragments may or may not be depending on their as of yet unknown ability to be used as a probe for screening as discussed above which rests on their identity with the DNAs present in the carcinomas and not in normal tissue.

Note that there are other uses of the polynucleotide which do not have utility under 35 USC 101/112, first paragraph. These are mentioned in the interest of

compact prosecution. Even though the approximate chromosomal site of the DNA is provided (1p36.11 region, p. 104-105), and there is a suggestion that aberration in this area of the chromosome are sometimes associated with cancerous cells or a predisposition to cancer, it is not disclosed which cancers are linked to that site. Also, Because zcytor19 DNA has not been shown to be involved in a cancer (though it could be a diagnostic marker for some cancers) and no abberation in zyctor19 as been shown to be associated with a cancer, the mapping does not provide a specific utility. Also, the use as a chromosomal marker is not specific since there are many polynucleotides in the prior art that could be used to tag chromosome 1.

It is stated that the present encoded polypeptide, which has not actually been expressed, is member of the type II cytokine receptor family, possessing several features in common with type II cytokine receptors (p. 19, two paragraphs beginning line 12). Because it is not know what ligand Zcytor19 binds, what the physiological outcome of ligand binding would be or what diseases it is specifically associated with, the encoding nucleic acid does not have a specific utility.

Priority

For purposes of prior art rejections, the instant application does not receive benefit of priority to either provisional application 60/267,211 or 60/253,561 because there is no disclosed use of the zyctor19 nucleic acid or polypeptide as required for benefit or priority. The effective filing date of the instant application is November 28, 2001.

35 U.S.C. § 119(e) states that:

> (e)
> (1) An application for patent filed under section 111(a) or section 363 of this title for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in a provisional application filed under section 111(b) of this title, by an inventor or inventors named in the provisional application, shall have the same effect, as to such invention, as though filed on the date of the provisional application filed under section 111(b) of this title, if the application for patent filed under section 111(a) or section 363 of this title is filed not later than 12 months after the date on which the provisional application was filed and if it contains or is amended to contain a specific reference to the provisional application. No application shall be entitled to the benefit of an earlier filed provisional application under this subsection unless an amendment containing the specific reference to the earlier filed provisional application is submitted at such time during the pendency of the application as required by the Director. The Director may consider the failure to submit such an

> amendment within that time period as a waiver of any benefit under this subsection. The Director may establish procedures, including the payment of a surcharge, to accept an unintentionally delayed submission of an amendment under this subsection during the pendency of the application....

Applicant is advised that the instant application can only receive benefit under 35 USC § 119(e) from a provisional application which meets the requirements of 35 USC § 112, first paragraph, with respect to the now claimed invention. The provisional applications do not meet those requirements and, therfoere, are unavailable for benefit of priority under 35 UCS § 119(e).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by GenBank Accession Number AL358412.8.

GenBank Accession Number AL358412.8 teaches a genomic DNA comprising a sequence identical to SEQ ID NO:1 of the instant application and fragments thereof and which, therefore, encodes a polypeptide of SEQ ID NO:2 and a polypeptide which comprises a fragment of SEQ ID NO:2. See attached "SEQUENCE COMPARISON".

Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,789,192 discloses a mammalian interleukin-10 receptor, which is a class II cytokine receptor and, therefore, related to the currently claimed receptor. The prior art does not teach the claimed polypeptide. The following Pre-Grant Publications by others are not available as prior art, but are made of record because they disclose a polypeptide identical to all or most of the Zcytor 19 of SEQ ID NO:2, 19 or 21: US20030180752A1, US20020142292A1, US20030158100A1.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (571)272-0873. Dr. Kaufman can generally be reached Monday, Tuesday and Thursday from 8:30AM to 2:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (571)272-0871.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Official papers filed by fax should be directed to (703) 872-9306. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Claire M. Kaufman, Ph.D.

Patent Examiner, Art Unit 1646

April 12, 2004